

HL

Notice of Allowability	Application No.	Applicant(s)	
	09/214,155	TAKAYAMA ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 20 October 2004.
2. ☒ The allowed claim(s) is/are 3-4 (renumbered as 1-2).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other: _____. |

[Handwritten signature]

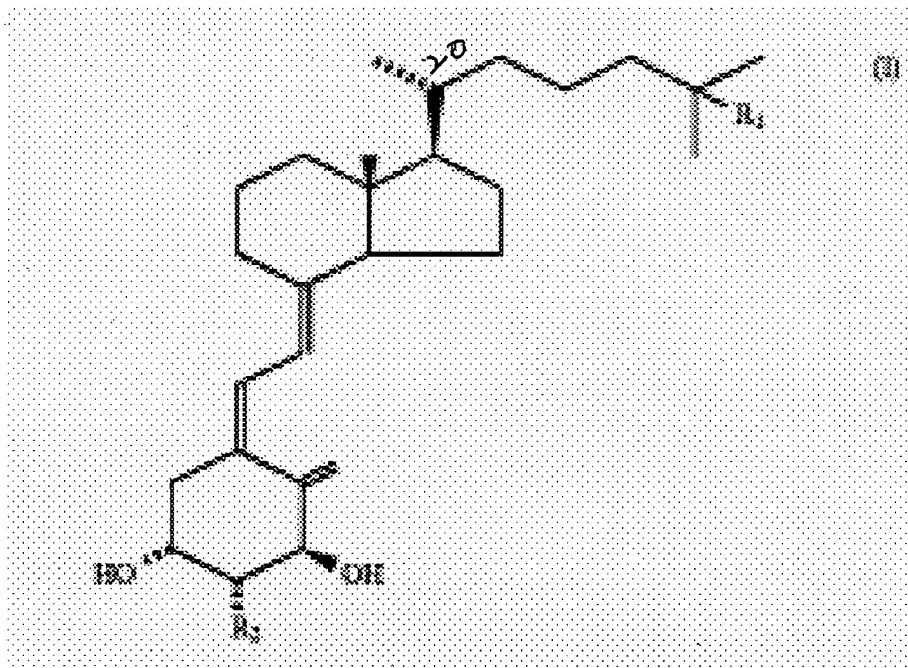
REASONS FOR ALLOWANCE

Claims 3 and 4 (renumbered as 1 and 2) are allowed because the side-by-side comparisons in the declarations filed by Applicants clearly shows that 20S form of vitamin D compounds are better than 20R. The data shows unexpected results in the activity of 20S vs. 20R. The data reveals that 20S forms are substantially more potent and require lower concentrations to induce cell differentiation.

Furthermore, the double patenting rejection was withdrawn because the copending application, 10/069481, was abandoned. The 103 rejection was withdrawn because the arguments were found persuasive.

The following is an examiner's statement of reasons for allowance:

The closest prior art, MIYAMOTO et al¹, is drawn to a compound of formula (I):



¹ United States Patent No. 5,877,168. See the entire document, especially the abstract, Examples 1, 6, 7, and 8, and claims.

Art Unit: 1616

Where R_1 represents a hydrogen atom or a hydroxyl group; and R_2 represents a straight-chain or branched C.sub.1 -C.sub.7 alkyl, C.sub.2 -C.sub.7 alkenyl or C.sub.2 -C.sub.7 alkynyl group, which is substituted with a hydroxyl group, a halogen atom, a cyano group, a lower alkoxy group, an amino group or an acylamino group.

In instant invention R_2 is methyl and R_1 is OH.

The instant invention of claim 3 differs from MIYAMOTO et al in being stereoisomers of the compounds US '168 (see especially example 6). Instant claims are drawn to 20S-form of vitamin D compounds of claim whereas prior art teaches 20-R form.

The results presented in Table 1 and Table 2 filed in the declaration shows the side by side comparison of the compound 68 (20S) with compound 65 (20R), compound 71 (20S) with compound 3 (20R), compound 74 (20S) with compound 6 (20R), and compound 72 (20S) with compound 4 (20R).

The data reveals that 20S forms are substantially more potent and require lower concentrations to induce cell differentiation. Example 6 of MIYAMOTO et al is the same as compound 65 i.e. differs at 20-position being an R-isomer.

The unexpected results of 20S-form of Vitamin D compounds when R_2 is methyl and R_1 is OH was neither taught nor suggested by the prior art.

Claim 4 is drawn to method of producing the compounds of claim 3. The data showing unexpected superior results of the product presented in claim 3, the process of claims 4 is allowed. (*In re Ochiai*, 71 F.3d 1565).

Art Unit: 1616

Examiner is thankful to Attorney Susan J. Mack for her cooperation during the prosecution of this case.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Friday, March 4, 2005